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K003156
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8.0 Special 510 k Summary

510 (k) Summary
Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

The Product
- BlastAssist System, Cat. No. 1739 and 1740

Indications for use:
BlastAssist System is designed for use from fertilisation through to blastocyst development.
BlastAssist System (Medium 2) can also be used as a vehicle during embryo transfer.

COMPOSITION:

Medium 1
- $MgSO_4$
- NaCl
- NaH_2PO_4
- K_2SO_4
- Glucose
- Pyruvate
- Lactate
- L-Glutamine
- Sodium Bicarbonate
- HEPES
- Non Essential Amino acids
- Taurine
- ART Supplement
- HSA
- Penicillin 50.000 IU/litre
- Streptomycin 50 mg/litre
- Phenol Red (Except product 1740)

Medium 2
- $MgSO_4$
- NaCl
- NaH_2PO_4
- K_2SO_4
- Glucose
- Pyruvate
- Lactic Acid
- L-Glutamine
- Sodium Bicarbonate
- Essential Amino Acids
- Non Essential Amino Acids
- ART Supplement
- HSA
- Penicillin 50.000 IU/litre
- Streptomycin 50 mg/litre
- Phenol Red (Except product 1740)

STABILITY, CYTOTOXICITY- AND BIOCOMPATIBILITY TESTING
Stability testing of BlastAssist System over 12 weeks has been performed (Appendix 1) and a shelf life of 6 weeks after production is recommended. Once opened the product is to be used within 7days.

Furthermore BlastAssist System was classified as non-toxic according to the Mouse Embryo test, non-irritant according to vaginal irritation test and showed evidence of delayed contact hypersensitivity in 2 out of 20 animals tested.

Product testing controls
1. Sterility test
2. Mouse Embryo test, two cell assay, Blastocyst rate > 80 %
3. Endotoxin test, LAL - ≤ 0.10 EU/ml.

4. pH
5. Osmolality

Note: The results from each batch are stated on a Certificate of Analysis, which is available upon request.

Clinical Documentation:
BlastAssist System was first tested in mouse studies, where it was compared to Medi-Cult's Universal IVF Medium (K 991279) plus M3 Medium (K991331). In contradiction to the Universal IVF / M3 system which gives a 2-cell block, the BlastAssist System gives embryos that develop to hatching blastocysts.

Based on this experience two clinical trials were performed. In the first trial Universal IVF/ M3 system was compared BlastAssist System Medium 1 and M3 Medium. The ongoing pregnancy rate per embryo transferred was 31.6 % with the current system and 44 % with the test system. Cycles with blastocysts at day 5 increased from 5 % with the current system to 35 % with the test system.

In the second study the above test system (BlastAssist System Medium 1/ M3 Medium) was compared to The BlastAssist System Medium 1 and Medium 2. Ongoing pregnancy rate per embryo transferred was 28 % with BlastAssist System medium1 / M3 Medium and 61.1 % with BlastAssist System. The cycles with blastocysts at day 5 increased from 40 % with BlastAssist System Medium 1 / M3 Medium to 88.9 % with BlastAssist System.

Additional clinical studies including 214 oocytes recoveries (Maribor study) and 109 oocytes recoveries (Oslo Study) resulted in clinical pregnancy rates per embryo replacement of 62.4 % and 35.3 %.

The studies show that BlastAssist System gives a high rate of blastocyst formation and high pregnancy rates when used in human IVF / ICSI. Clinical pregnancy rates per embryo replacement above 50 % were obtained with less than two embryos replaced on average. Replacement of embryos at day 4 or 5 after fertilisation gave similar results.

BlastAssist was marketed in Europe in March 2000. There have been no registered complaints on the product and no evidence that the product has been the cause of any serious adverse events in connection with its intended use.

Thus based on the clinical data presented we feel that the safety and effectiveness of the product for its intended use is shown in the present submission and the products is substantially equivalent to the predicated device Medi-Cult's Universal IVF Medium (K 991279) plus M3 Medium (K 991331).

Prepared and Submitted by:

October 10, 2000

Ronald G. Leonardi, Ph.D. Date
President
R & R REGISTRATIONS
P.O. Box 262069 San Diego, Ca 92131
619-586-0751

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2001

Medi-Cult a/s
c/o Ronald G. Leonardi, Ph.D.
President
R & R Registrations
P.O. Box 262069
SAN DIEGO CA 92196-2069

Re: K003156
BlastAssist System
Dated: December 26, 2000
Received: December 28, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Dr. Leonardi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K003156

510(k) Number (if known)

Device Name: Medi-Cult BlastAssist System

Indications for Use:

BlastAssist System is designed for use from fertilisation through blastocyst development.

BlastAssist System (Medium 2) can also be used as vehicle during embryo transfer.

(PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Syson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003156